

PCT



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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 661925 | FOR FURTHER ACTION | | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No. PCT/JP00/03943 | International filing date (day/month/year) 16/06/2000 | Priority date (day/month/year) 02/07/1999 | |
| International Patent Classification (IPC) or national classification and IPC C12N15/12 | | | |
| Applicant SAGAMI CHEMICAL RESEARCH CENTER et al. | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application | | | |
| Date of submission of the demand 22/01/2001 | | Date of completion of this report 23.10.2001 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Hoff, C Telephone No. +49 89 2399 7895  | |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP00/03943

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-84 as originally filed

Claims, No.:

1-7 as originally filed

Drawings, sheets:

1/10-10/10 as originally filed

Sequence listing part of the description, pages:

1-59, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 1-7 (partially).

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 1-7 (partially).

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

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- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☐ not complied with for the following reasons:
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-7 (partially).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | |
|-------------------------------|-----------------|
| Novelty (N) | Yes: Claims 1-7 |
| | No: Claims |
| Inventive step (IS) | Yes: Claims |
| | No: Claims 1-7 |
| Industrial applicability (IA) | Yes: Claims |
| | No: Claims 1-7 |

**2. Citations and explanations
see separate sheet**

The following documents are referred to :

- D1:** WO 86 01532 A (CELLTECH LTD) 13 March 1986 (1986-03-13)
D2: WO 98 21328 A (KATO SEISHI ;PROTEGENE INC (JP); SEKINE
SHINGO (JP); SAGAMI CHEM R) 22 May 1998 (1998-05-22)

III. Non establishment of an opinion

No search report was established on the subject matter relating to the inventions 2-10. In consequence no opinion on novelty, inventive step and industrial applicability was formulated on the subject matter of these inventions.

IV. Unity

The Preliminary Examination Authority agrees with the objection of lack of unity put forward by the International Searching Authority according to Article 17(3)(a) PCT.

The Applicant didn't comply, within the prescribed time limit, with the invitation to pay additional search fees (letter of 13.11.2000). In consequence the International Preliminary Examining Authority establishes the preliminary examination report on those parts of the application which relate to what appears to be the main invention, for which a search report was established.

The first invention relates to a polypeptide of SEQ ID NO:1, its corresponding nucleic acid sequences of SEQ ID NOs:11 and 21, an expression vector capable of expressing said polypeptide and an antibody against said polypeptide. This invention relates to claims 1-7 partially.

V.1 Novelty

SEQ ID NO:1 presents 65 % identity over 223 amino acids overlap with Human pregastric lipase protein.

SEQ ID NO:11 presents 73.6% identity over 656 nucleotides overlap with the mRNA sequence of Homo Sapiens human gastric lipase.

In consequence claims 1-7 are novel over the prior art under article 33(2) PCT.

V.2 Inventive step

The present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 1-7 does not involve an inventive step.

The closest prior art is represented by D2.

D2 discloses several cDNAs encoding human proteins having transmembrane domains.

The difference between the present application and D2 is the provision of other cDNAs encoding proteins harbouring transmembrane domains.

The problem to be solved in the application is the provision of a further nucleic acid sequence encoding proteins with transmembrane domains.

The solution is provided by the sequences of SEQ ID NOs:1, 11 and 21.

The person skilled in the art would be able to isolate nucleic acid molecules encoding proteins with a transmembrane domains by using methods of routine. Therefore claims 1-4 are not considered as involving an inventive step under Article 33(3) PCT.

As a consequence, an expression vector expressing said protein, a transformed eucaryotic cell expressing said protein and an antibody directed to said protein are also not considered to involve an inventive step .

V.3 Industrial applicability

The present application does not meet the requirements of Article 33(4) PCT, because the subject-matter of claims 1-7 is not industrial applicable.

The specific function of the cDNA and the corresponding encoded transmembrane protein is not disclosed in the application. In the description it is speculated that the protein is essential in tissue growth, hormonal regulation, regulation of haematopoiesis and several other biological processes.

As long as there is no indication of a specific function of said protein and corresponding nucleic acid it is not clear how the subject matter disclosed in the present application is industrially applicable.